IMPACT OF NUTRITION INTERVENTIONS ON SYMPTOMS OF POLYCYSTIC OVARIAN SYNDROME (PCOS) AMONG WOMEN OF REPRODUCTIVE AGE (20-45 YEARS)

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Submitted by

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a) Title of the Thesis : "Impact of Nutrition Interventions on symptoms of Polycystic Ovarian Syndrome among Women of Reproductive age (20-45 years)"

b) Brief Description on the state of the art of the research topic

Current era has witnessed increased reproductive health issues among adolescent girls, young women of reproductive age and also post-menopausal women. Female infertility posed the main threat among the reproductive age women. Polycystic ovarian syndrome is one of the top ranked heterogeneous disorders encompassing reproductive, metabolic and hormonal dysfunction and has higher interrelation to pregnancy complications and pregnancy outcome. The prevalence is intensifying in developing countries like India and the root causes are rapid nutritional transitions due to westernized diet and lifestyle pattern. Nutrition and health are intimately connected throughout the lifecycle of an individual. Among various nutrients, micronutrient status is critical to the health of women, particularly during their reproductive age and stage.

The jeopardy of PCOS in reproductive age group is very intrusive which exposes symptoms such as infertility, dysmenorrhoea, obesity, cardio vascular diseases, diabetes mellitus, and other psychosocial abnormalities .The necessity for efficacious method is in the leading edge to reduce these health risks. The focus, to date, has been on the macro and micronutrient components of the diet. Strong evidence supported the use of dietary interventions including principles of macro and micro nutrient balance in the management of PCOS. Dietary intervention is expected to enhance nutritional and health status and to relieve the metabolic, hormonal and physiological symptoms related to PCOS among young women of reproductive age. Nutritional supplement in the form of Nutrient dense health mix is thought to enhance the reproductive environment by helping body fat reduction, restore micronutrients, strengthening the antioxidant defence system, with the clinical benefits of improving hyperandrogenism, oocyte and embryo quality, reducing the time to conception, and increasing the chances of becoming pregnant in the right age.

c) Definition of the problem

The prevalence rate of Poly Cystic Ovarian Syndrome is widely varying as 2.2-26 percentage globally (Gowri and Ramana,2020) and 3.7 to 22.5 percent among Indian women of reproductive age (Gaine et. al., 2019). The role of specific micronutrients and bio active compounds in the form of ready to use Nutritional supplement of Health mix powder in reducing the symptoms are very relevant compared to all other commercial expensive medical therapies in the treatment of PCOS. From the literature review, it is noted that the research studies so far done were about the role of macronutrients on PCOS and multiple micro nutrient supplementation in reducing PCOS symptoms including betterment of

pregnancy rates among PCOS subjects Foroozanfard (2015), Jamilian et al, (2015) and Moran(2017). The assessment of micronutrient intake among the PCOS women and formulation of an indigenous micronutrient rich health mix powder considering the lacunae in the micronutrient intake of the targeted subjects is the concept of the present research study. In this context, the present study is relevant as it focused on incorporating the relevant micronutrient rich, low cost and locally available grains and seeds into a nutritional supplement health mix powder to intervene on the selected PCOS population and to study the effect of nutrition intervention on nutritional status, biochemical and clinical symptoms of PCOS among the selected participants.

d) Objectives and Scope of the Present Research Study

- Find out the incidence of PCOS among women in the reproductive age (20-45 years)
- Identification of women having PCOS for collection of data related to socio economic profile, dietary and lifestyle pattern ,nutritional , reproductive, and health status
- Assessment of nutritional status and nutritional knowledge of the selected women
- Formulation and evaluation of nutrient dense health mix and nutrition education modules for nutrition interventions and
- Impact of nutrition interventions on nutritional status nutrition knowledge and on the symptoms of Polycystic ovarian syndrome among women of reproductive age (20-45 years)

e) Methodology

Phase I Incidence of PCOS among women in the Reproductive age (20-45 Years)

In the present study, women of reproductive age group of 20-45 years consulted in the Gynaecology and Dietetics Outpatient Department of Believers Church Medical College Hospital, Thiruvalla, Kerala between January 2019 and June 2020 were screened for the study. A quick screening was carried out using validated tool Rotterdam criteria (2003) to identify the symptoms of PCOS among 810 women in the age group of 20-45 years and 284 subjects having PCOS were identified and selected for the study on the basis of inclusion and exclusion criteria.

PHASE - II: Assessment of Nutritional status and identification of symptoms related to PCOS

The purposive sampling survey was carried out to collect the data. Interview schedule cum specially designed questionnaire consisting demographic, dietary and lifestyle pattern, reproductive, menstrual history and food frequency were used to collect data.

Questionnaire, was filled during face to face interview both in paper and the "*google docs"* forms for easiness of analysis by the investigator. The socio economic profile of the selected women was analysed using Kuppuswamy Socioeconomic Scale (2020). Anthropometric measurements weight, height, BMI, WHR, body fat, and TSF were recorded using standard procedures. Menstrual history related to menstrual irregularity, features of hyperandrogenism, and family history of PCOS, infertility, was collected (and clinical examination was conducted. The selected women were screened for clinical signs of hyperandrogenism (acne, oily skin and hirsutism).Modified Ferriman-Gallwey (FG) score, Global Acne Grading System, Perceived Stress Scale, and Godin Leisure time Scale were used as the tools for assessing hirsutism, acne, stress and physical activity level respectively. Ultrasonography was also used to detect PCOS among the selected women. On the day of data collection, random blood glucose level, lipid profile, haemoglobin level and total testosterone level were analysed. Additionally, blood pressure was also measured for the selected women in sitting position, and >/= 130/85mmhg was considered as hypertension. Total testosterone values were analysed as a part of hormonal assay in biochemical estimation

PHASE - III: Formulation and evaluation of Nutrient dense Health mix powder

Finger millet and pearl millet were germinated and dried, then introduced in different proportions after slight roasting to make the suitable variation. Other ingredients like flax seeds, pumpkin seeds, sunflower seeds, sesame seeds and brown sugar were mixed in different combination and ratio. All the processed ingredients were ground into powder for ready to consume form. Analysis of macro and micro nutrients in the Health mix powder was carried out using the standard methods. Sensory evaluation in terms of appearance, colour, taste, flavours and texture were considered and grades were given according to the degree of acceptance by the selected taste panel members. The highest scored variation was selected for the nutrition intervention and nutrient analysis was carried out. Packing was manually done in a standard aluminium foil packing and was kept in air tight containers for storage. Microbial count of the nutritional supplement was done and the shelf life was analysed in the first month, second month and third month.The supplement was prepared without preservatives and distributed periodically to the selected participants. Thes participants were also asked to keep the supplement in the refrigerator throughout the intervention period of 90 days.The ingredients used in the nutritional supplement were locally available and low cost and were rich in micronutrients. Cost effectiveness was also calculated.

PHASE – IV Effect of Nutrition interventions on symptoms, nutritional status and knowledge of women having PCOS

Nutrient dense health mix supplement in the form of ready to consume powder (300g) in the airtight sealed container was distributed once in 10 days. All the selected participants in the Experimental group I (N=32) were properly instructed to consume in the morning 15g and in the evening 15 g daily without any wastage for three months . Nutrition education was followed with dietary intervention for 90 days .Selected 31 participants in the Experimental group II were provided nutrition education.The educational modules were prepared by including a brief introduction, pathophysiology, prevalence, aetiology, signs and symptoms, consequences, nutrition and dietary management related to PCOS and also stress relieving techniques by including suitable literatures and pictures related to PCOS. Booklet, Leaflets and Powerpoint presentation were prepared and nutrition education sessions were executed as one to one counselling initially. Group discussion was carried out on the specified days and leaflets were also distributed to enhance their nutritional knowledge. The participants undergoing medical support for PCOS was considered as control group.Anthropometric measurements, biochemical estimation, clinical examination and individual dietary intake using three day food record and 24 hour recall method were also used to assess the nutritional status and also nutritional knowledge of the selected participants before and after the nutrition intervention for the period of 90 days .

V. Data collection and Statistical Analysis

Descriptive measures were analyzed using percentage, Mean $\pm$SD. Categorical variables were compared using the Mc Nemar's χ^2 test and Mc Nemar's odds ratio.Inferential statistics like correlation and chi-square were applied to find the association and differences between the variables.Paired t- test was applied for numeric variables such as weight, waist hip ratio, BMI and so on . Comparison of means performed using independent sample T-test. Paired *t*-test was performed to determine the significance of within-group change. Three -group comparison was performed by one way ANOVA (analysis of variance) after adjusted for the baseline values.The data was analyzed using SPSS 23 version.

f) The salient findings of the present study are highlighted in the following pages

- The interview and observational methods were used for the data collected and revealed that, in the present study majority of the selected women (56.7 per cent) were from semi urban areas followed by 33.5percent from urban areas and rest of them (9.5 per cent) were from rural areas. Among the 284 PCOS women, 44.8 per cent were Hindus 45.4 per cent were Christians and 9.8per cent were Muslims. Among the reproductive age women, 63 per cent were married, 36 per cent were unmarried and one per cent was separated.

- It is interesting to note that cent per cent of women had secondary education including graduation. It was interesting to note that none of the women enrolled in the study was illiterate or had primary education .Majority of the women were under graduates (50.7 percent),23 percent were post graduates and only 1.3 percent were Diploma holders. The present study also revealed that only 40.9 percent of women were employed, meagre percent were involved in business, rest of the selected women were either unemployed (42.6%) or students (15.8 %).Majority of the women (59.2%) were home makers. Among the employed women, 31.6percent were engaged in Professional job in various organisations and rest of them were self employed .
- Regarding the Socio economic status of the women, 39 percent were from lower middle income group,33 percent were from upper middle income group, 17.5 percent were from upper lower income group and 1.5 percent was from lower income group. About nine percent of women were from upper income group.
- The mean age of the selected women in the study groups was 29.3±7.1 years. Among the selected women,40.1percent were in the age group of 20-25 years, 19 percent of women were in the age group of 26-30 years, 17.3 percent were in the age group of 31-35 years and 23.6 percent were 35 years of age above. BMI classification was computed on the basis of Asian Classification of BMI. Meagre (two) per cent of the selected women were in obese grade III or morbid obese category. Among the selected women, 34.5 per cent were obese II category and 34.1 percent were in the obese grade I. Overweight and normal weight category were exactly the same (13.4 per cent), whereas 4.6 per cent were underweight category.
- Profile of Clinical examination revealed that around 45 per cent of the selected women experienced hirsutism as a clinical sign of hyperandrogenism.Fourty eight percent had Acanthosis nigricans and androgenic alopecia, 41 per cent had acne, more than 60 percent of selected women had depression , anxiety and mood swings .More than 78 percent of the selected women had regular sleep and 17.9 percent had a mildly elevated BP level (=>130/85mm of Hg) and rest of them had normal blood pressure.
- Before nutrition intervention, systematic grouping of the 93 PCOS participants into Experimental groups I,II and Control group were carried out on the basis of anthropometric measurements and clinical symptoms. The mean age of the Experimental group I was 25.97 ± 4.78, for Experimental group II 27.84 ± 5.38 and for Control 25.00 ± 5.45. The mean BMI was 29.95 ± 4.35 for Experimental group I ,

30.82 ± 5.82 for Experimental group II and 30.43 ± 4.18 for Control group.All the anthropometric variables were comparable before nutrition intervention and there was difference in age, weight, BMI, TSF, WC, HC, Body fat, Body water and Visceral fat among the selected participants of the study groups.

- The effectiveness of the Nutrition interventions in terms of dietary supplementation and nutrition education on anthropometric measurements using Paired sample t test revealed that there was a significant reduction in weight, BMI, Waist circumference, Hip circumference, body fat and Visceral fat levels ($p<001$). The mean weight reduction in the three month period was 4.7kg in Experimental group I. The reduction in BMI, TSF, waist circumference, hip circumference, and body fat was 1.9kg/m^2,1.4mm, 1.5 Inches ,1.08 Inches and 1.5 percent respectively. However there was no significant difference in waist hip ratio ($p=0.324$) and body water ($p=0.968$) of the selected participants in Experimental group I.
- A significant difference in values before and after nutrition intervention was observed among the experimental II group. Weight ,BMI ,TSF and body fat were observed to be decreased as 1.9kg,1kg/m^2, 0.54mm, 0.72 per cent respectively ($p<0.001$). Waist circumference ($p=0.640$), Hip circumference($p=0.541$) and body water($p=0.682$) had shown that there was no significant impact due to the nutrition education.
- Among the Control group, there was no significant reduction in any of the anthropometric measurements ($p>0.05$) except for waist hip ratio ($p=0.004$) during the study period .It might be due to their regular use of medications, even before the nutrition intervention.

- Comparison of Effectiveness of nutrition interventions between the study groups by't' test concluded that no significant difference in weight, TSF, Body water and visceral fat between the Experimental I and Experimental II group. No significant difference in weight, TSF, waist circumference, hip circumference, body fat percentage, body water and visceral fat between Experimental I and Control group after the nutrition interventions. Significant difference ($p=0.0228$) in BMI was observed between Experimental I and Control group. A significant difference in Waist circumference ($P=0.015$), Hip circumference ($p=0.0154$) and body fat percentage ($p=0.0268$) was noted between the participants of Experimental I and Experimental II groups.
- Comparison of Anthropometric measurements between the study groups before and after nutrition interventions revealed that there was a significant mean weight reduction in Experimental group I when compared to the Experimental group II. The Control group differed significantly from the Experimental I group. A significant difference between the Experimental II and Control group was also observed. The

Mean difference in reduction of BMI between Experimental II (M=1.003, SD=1.270) and Control groups (M=-.100, SD=1.304) differed significantly from the Experimental Igroup I (M=1.88 SD=1.07). The mean difference in waist circumference after supplementation in Experimental group I differed significantly from Experimental group II. No significant difference was observed between Experimental group II and control group. Significant difference in hip circumference between Experimental group I and Experimental group II were observed, but the difference was not significant between Experimental II and Control groups. The mean difference in body fat percentage in Experimental I differed significantly from Experimental II and Control groups. No significant difference observed between Experimental II and Control (p>0.05) groups. There was no significant difference between any of the nutrition intervention groups in terms of mean Waist Hip ratio ,Triceps skin fold thickness ,Visceral fat and Body water (p>0.05)

- After three months of nutritional supplementation in Experimental group I, there was a significant reduction in the serum cholesterol level (p=0.032), Triglycerides (p=0.046), Low density Lipoprotein (0.026) Cholesterol to HDL ratio (p=0.002) and testosterone level (p=0.002), whereas HDL level had shown a significant increment. There was no significant difference (p>0.05) in the value of haemoglobin, random blood sugar and VLDL of the participants before and after the nutrition interventions.
- After three months of nutrition education in the experimental group II ,there was a significant increase in the serum HDL level. Within group, comparison of HDL has shown a significant increment in the mean values (p=0.005).There was no significant difference in the values of haemoglobin, random blood sugar, Triglycerides, total cholesterol, LDL, Cholesterol to HDL ratio and VLDL levels (p>0.05)before and after nutrition interventions .There was a meagre difference in the values of testosterone with a mean difference of 0.002ng among the participants, before and after nutrition education.
- In within group comparison, a significant marginal decrease in serum cholesterol level was observed in Control group with a mean value of 9.30±24.83mg (p=0.049). In Control group, there was no significant difference and was noted in the post nutrition intervention in terms of the parameters of TG, HDL, LDL, and Cholesterol to HDL ratio, VLDL and Testosterone levels.
- Comparison of Biochemical profile following interventions and the effectiveness between the study groups by't' test revealed that none of the biochemical parameters showed significant difference between the Experimental I and Experimental II groups. Between Experimental I and Control group, there were no significant difference in all

biochemical parameters except for Triglycerides (p=0.0482).It might be due to short duration of nutrition interventions.

- Comparison of Biochemical parameters between the three groups to determine the efficacy of the nutrition interventions indicated that the mean Cholesterol difference of Experimental I group (M=11.28 SD=28.439) was significantly reduced when compared to the Control group (M=-9.30, SD=24.833), but no difference was observed between Experimental I and Experimental II groups .The difference in TG values showed significant difference between Experimental I (M=17.218, SD=46.873) and Control (M=-7.56, SD=45.37), but was not significantly differed from Experimental II group(M=6.612, SD=23.408).The difference in cholesterol to HDL ratio indicated that there was a significant difference between the Experimental I(M=0.556,SD=0.905) and Control (M= -.1233, SD =0.948) but no significant difference between Experimental I and Experimental II group. In terms of testosterone changes Experimental I (M=0.145, SD 0.238) showed significant difference with Experimental II (M=0.0023, SD=0.0646), difference was remarkable between Experimental I and control group (M=-0.0147, SD=0.1167). Experimental I group had significant reduction in total cholesterol levels, Triglycerides Cholesterol to HDL ratio and total testosterone levels. Haemoglobin levels had a significant increase (M=.1531, SD=.997) within the group as evidenced by paired sample t test.In the control group the only significant difference between the treatment effects was seen in cholesterol levels. In the nutrition education group, Haemoglobin , Random blood sugar Cholesterol , TG ,LDL,HDL , Cholesterol to HDL ratio, Total testosterone level any of the variable has shown significant difference within the group.
- Level of regularisation of menstrual cycle showed that there was no significant association of menstrual cycle regularity between the study groups before nutrition interventions. The selected participants in the experimental group I had 9.1 times higher chance of getting regular periods than those on experimental II group (nutrition education alone) (OR: 9.1,CI 2.84-29.146) and 4.3 times higher chance of getting regular periods compared to the control group (OR:4.33 CI 1.385-13.552).
- The significant difference was noted in the study groups by reducing the symptoms of acne and stress level .The scores of physical activity of the participants of the study groups also showed a significant difference(p<0.001) with a mean increase of (5.03± 8.26) after the nutrition interventions. No significant difference seen in the hirsutism level before and after nutrition interventions. The stress score before and after intervention within the group was significantly reduced with a mean decrease of

(M±SD 4.2188±56), (M±SD 6.35±7.3191), (M±SD 3.1 ± 5.54) among the experimental I group, Experimental II group and control group respectively ($p<0.001$).Hirsutism, acne and physical activity levels were not significantly differed among the participants in the Experimental II and Control groups.

- In all the three study groups, the stress level was reduced considerably and physical activity level was improved between the selected participants.

g) Paper Published

- Comparison of Clinical Findings and Nutritional Status in Women with Polycystic Ovarian Syndrome in 18-29 and 30-45 Year Age Groups, published in The Indian Journal of Nutrition and Dietetics, Vol.58, No.3 July –September 2021,ISSN:022-3174;online ISSN :2348-621X
- Clinical and Biochemical profile of Polycystic ovarian syndrome among adult women of reproductive age (20-45 years) , Published in Natural Volatiles &Essential Oils 2021 e-ISSN2148-9637 Vol.8,Issue5, page,9043-9055
- Symptoms ,risk factors and dietary pattern of Women of Reproductive age (18-45 years) having Polycystic Ovarian Syndrome published in a book titled " Food and Nutrition to transform the future" (2020)ISBN 9789385604126"
- Effectiveness of Micronutrient rich supplement on the symptoms of Polycystic Ovarian Syndrome among Reproductive age women, published in International Journal of Health Sciences,2022e-ISSN:2550-696X, p-ISSN:2550-6978. Vol6, No S1 Pageno:14128-14144
- Symptoms of Polycystic Ovarian Syndrome among Women of Reproductive Age (18-45 years) Published in Research Highlights 2020 ISSN :2231-2374

h) Paper Presented

- Oral Presentation on "Symptoms ,risk factors and dietary pattern of Women of Reproductive age (18-45 years) having Polycystic Ovarian Syndrome" at 33rd Biennial Conference of Home Science Association of India 2021. Avinashilingam Institute for Home Science and Higher Education for Women Coimbatore
- Oral Presentation Management of Maternal Nutrition in the context of Covid 19" at the National Webinar on"Covid 19: Pregnancy, Childbirth and Postnatal care", conducted on 14.09.2020
- Poster Presentation on "Impact of Nutrition Intervention on the symptoms of Polycystic Ovarian Syndrome among Women of Reproductive age "held on the Believers Church Medical College Hospital Annual Research day, 5th December 2018.

- Poster Presentation on “Effectiveness of Nutrient dense health mix powder on symptoms of polycystic ovarian syndrome among reproductive age women” in the International conference on Critical care Nutrition held at Caritas Edu city, 2nd July 2022

i) Awards Received

- Received 3rd Prize for Poster Presentation “Impact of Nutrition Intervention on the symptoms of Polycystic Ovarian Syndrome among Women of Reproductive age” held on the Believers Church Medical College Hospital Annual Research day, 5th December 2018.
- Received 1st prize for Poster presentation “Effectiveness of Nutrient dense health mix powder on symptoms of polycystic ovarian syndrome among reproductive age women” in the International conference on Critical care Nutrition held at Caritas Edu city, 2nd July 2022

j) Conclusion

In the Nutrition Intervention group, there was a significant reduction in Weight, BMI, Waist circumference, Hip circumference, body fat and Visceral fat levels ($p<001$) with a mean weight reduction in the three month period was 4.7kg .The reduction in BMI, TSF, Waist circumference, Hip circumference, and Body fat was 1.9kg/m^2,1.4cm, 1.5cm, 1.08cm and 1.5% respectively. Regarding the biochemical profile, Haemoglobin, Total cholesterol, Triglycerides, Cholesterol to HDL ratio and total testosterone levels showed significant difference between the pre and post intervention. Acne and stress score has reduced considerably and physical activity score has increased consistently in the nutrition interventions group. Between the group comparison results showed significant reduction in weight, BMI ,TSF, WC, and HC was observed, but no difference in Body fat , body water and visceral fat between the groups .Cholesterol ($p=0.004$) , Cholesterol to HDL ratio ($p=0.0017$) and Testosterone($p=0.00$) levels has shown significant reduction between the groups .Regularity of association of Nutrition interventions with menstrual cycle revealed that the Nutrition intervention had 9.1 times higher chance of getting regular periods than those on nutrition education alone. There was a significant considerable decrease in the mean value of Stress Scores in the dietary supplementation, nutrition education and control groups. Scientific Evidences gathered for the present study revealed that there was a significant reduction in the PCOS symptoms experienced by the participants in the Experimental groups. Overall 6 percent reduction of weight in the experimental group I was effective in regularising menstrual cycle, reducing stress

and biochemical profile including testosterone levels, cholesterol and Triglycerides. This might be due to the Nutrient Dense health mix powder consumption for 90 days. Same dietary supplement with proper nutrition knowledge related to PCOS may be continued for a long period helps to prevent or minimize the complication and consequences of PCOS and to precipitate for healthy and happy life.

The study emphasized that the nutrition interventions including nutrient dense health mix supplementation, nutrition education programme, lifestyle modification, adoption of physical activity in their routine life and stress management are the integral components in the management of PCOS .These lifestyle modifications are recommended as the effective strategy for the treatment of PCOS by easing or relieving symptoms ,promoting their health status especially reproductive health and also enhancing the quality of life.

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Ethical Consideration

- Ethical approval from the Institutional Human Ethics Committee of Avinashilingam Institute for Home Science and Higher Education for Women. Coimbatore. The approval number is **AUW/IHEC-1920/FSN/FHP-01.**Ethical approval from Believers Church Medical College Hospital Thiruvalla, Kerala was obtained before proceeding with the research study and its approval number is **BCMCH/IEC/2020/02/126** respectively.

Recommendation

- This research findings are highly useful and effective for the women having PCOS Nutrition supplementation including nutrition and health education are the sustainable measures for improving the reproductive health and reducing symptoms associated with PCOS.
- Stress relieving techniques used in the study such as progressive muscle relaxation and mind relaxation techniques will be effective in reducing stress and anxiety of an individual.
- Micronutrient supplementation in suitable amounts in the form of indigenous health mix will be effective in reducing the consequences and symptoms of PCOS among young women.
- Regular consumption of macro and micronutrients rich foods in adequate quality and quantity is an effective sustainable strategy in promoting overall health status including reproductive health in regularising menstrual cycle, minimizing the complications and consequences of reproductive health issues like PCOS.This will conclude that nutrient dense health mix is the most suitable appropriate and

feasible attempt in alleviating the symptoms of PCOS and in improving nutritional status of the targeted population.

- More studies on the effect of long term nutrition intervention on large sample size will be needed.

k) References

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